

PSJ3
Exhibit 339C

testify to her reason for refusing to fill the prescription. Ms. Cohalla is expected to testify to what procedures, if any, were implemented in light of Mr. McCune's attempt at filling a fraudulent prescription. She is also expected to testify regarding Walgreens #03629's filling of subsequent prescriptions for Mr. McCune through October 2011 despite Mr. McCune's previous history of prescription fraud and despite the latter travelling a long distance to fill these prescriptions. Ms. Cohalla is expected to testify to prescriptions filled by Walgreens #03629 by other individuals residing in faraway locations such as Ohio, Kentucky, Tennessee, Colorado and Missouri. She will testify to whether prescriptions presented by these individuals presented any red flags for the on-duty pharmacist and whether pharmacy personnel attempted to resolve these red flags.

7. Stuart Eakins' proposed testimony:

Stuart Eakins (Mr. Eakins) will testify to his training and experience as Pharmacy Manager for Walgreens #03629. Mr. Eakins is expected to testify to what procedures, if any, were implemented in light of Mr. McCune's attempt at filling a fraudulent prescription. He is also expected to testify regarding Walgreens #03629's filling of subsequent prescriptions for Mr. McCune through October 2011 despite Mr. McCune's previous history of prescription fraud and despite the latter travelling a long distance to fill these prescriptions.

Mr. Eakins is expected to testify regarding guidelines and procedures for filling questionable controlled substance prescriptions. He will be asked to testify about red flags for diversion and abuse and how pharmacy personnel would try to resolve those red flags.

8. Patricia Gibson's proposed testimony:

Patricia Gibson (Ms. Gibson) will testify to her training and experience as Pharmacy Manager for Walgreens #03629. Ms. Gibson is expected to testify regarding Walgreens #03629's procedure for filling central filled prescriptions. She will be asked specifically about 25 prescriptions randomly selected by Investigator Flagg, and the pharmacy's failure to properly execute these prescriptions with the "CENTRAL FILL" designation as required by 21 C.F.R. § 1306.27(a). Ms. Gibson is also expected to testify to Walgreens #03629's filling of additional prescriptions for controlled substances that did not comport to the requirements of 21 C.F.R. § 1306.05 (i.e., prescriptions that did not contain the DEA registration number, full address and manual signature of the practitioner).

9. Mary E. Chmielewski's proposed testimony:

Mary E. Chmielewski (Dr. Chmielewski) will testify regarding her education, background, training, and experience as Senior Personnel Psychologist in the Research and Analysis (HRN), Human Resources Division of DEA. Dr. Chmielewski will be offered as an expert on relevant statistical data involving the sale and purchase of controlled substances by a DEA registered pharmacy.

Dr. Chmielewski will testify that in the course of her official duties, she frequently performs statistical analysis and interpretation. She has performed a statistical analysis of the ARCOS data related to oxycodone purchased by Walgreens #03629 for the period of January 2006 through December 2011. She is also expected to testify to her review of data compiled by Investigator Flagg regarding oxycodone purchases by 14 pharmacies in the 34997 zip code where Walgreens #03629 conducts business.

Dr. Chmielewski will testify that in analyzing the purchase data of Walgreens

#03629, she employed the Chi Square (Goodness of Fit) test. The Chi Square test is an inferential statistical test used to detect group differences using frequency (count) data and is among the most frequently reported analyses in research journal articles. In short, the Chi Square test is used to evaluate the number of observations that fall in two or more categories. Goodness-of-fit refers to whether a significant difference exists between a given set of observations and an expected number of observations based on chance. The expected number of observations is the likelihood to occur by chance and the actual observations are the collected data. Dr. Chmielewski will testify that with regard to her analysis of oxycodone purchase data by Walgreens #03629, it was determined that a statistically significant difference for orders from 2006 through 2011 was greater than what would be expected to occur due to chance or probability. She will therefore conclude that the volume increase of Walgreen #03629's purchases of oxycodone over this period of time was statistically significant.

10. Professor Paul Doering's proposed testimony:

Professor Paul Doering, M.S. (Prof. Doering) will testify regarding his education, background, training, and experience as a pharmacist. Prof. Doering will testify that he (1) is a registered pharmacist in the states of Florida and North Carolina, (2) is certified as a Consultant Pharmacist in Florida, (3) previously practiced in the community pharmacy setting (4) has been a professor at the University of Florida's School of Pharmacy for the past 35 years, (5) currently serves at the University of Florida's College of Pharmacy as Distinguished Service Professor of Pharmacy Practice, Emeritus, and (6) for 28 years was either Director or Co-Director of the University of Florida's Drug Information and Pharmacy Resource Center, a telephone access service through which

health professionals can get obtain information about drugs or drug therapy. Prof. Doering will further testify about his experiences serving as an expert consultant and witness in a number of criminal, civil, and administrative proceedings. Prof. Doering will provide expert witness testimony as detailed below.

Prof. Doering will testify about the education and training pharmacists receive in pharmacy school, including learning the fundamentals of both state and federal pharmacy law as it relates to the filling and dispensing of prescription drugs in general, and controlled substances in particular. He will further testify about training pharmacists receive in the application of those laws to real life situations. He also will discuss the coverage of these topics in Florida's pharmacist licensing exam.

Prof. Doering will testify about the epidemic of prescription drug diversion and abuse in the state of Florida. He will discuss the 2011 State of Emergency declared by the Florida Surgeon General which was issued in effort to prevent the many drug overdose deaths from controlled substances. The controlled substances commonly associated with this epidemic are Schedule II pain relievers such as oxycodone; Schedule IV benzodiazepines, such as alprazolam; and Schedule IV muscle relaxers, such as carisoprodol. Prof. Doering will testify about the overdose deaths due to oxycodone and benzodiazepines identified by the 2011 Florida Medical Examiners Report. He will testify that pharmacists are in a key position to reverse the trend of this epidemic.

Prof. Doering will further testify about the pharmacist's role in the distribution of prescription drugs that are controlled substances. He will testify about the dangerous propensities of certain controlled substances, in particular opiates and opioids such as oxycodone and benzodiazepines such as diazepam (Valium) and alprazolam (Xanax).

Prof Doering will testify that when controlled release opiate products are prescribed correctly, patients should not need to be on concurrent around the clock opiates for break through pain.

Prof. Doering will discuss the responsibilities of pharmacists in filling controlled substances prescriptions. He will testify about the review and analysis pharmacists should undertake before certifying any such prescription for release to the patient, including checking the licensing status of prescribers and evaluating whether the prescription presented to them is for a legitimate medical purpose and issued by a properly registered practitioner in the usual course of professional practice.

Prof. Doering will further testify about the “red flags” used by pharmacists as indicators of diversion and abuse. Because of the enormous abuse and diversion associated with oxycodone, the mere fact that an oxycodone prescription is being presented should put the pharmacist on full-alert to ensure that the prescription is valid. Oxycodone prescribed in combination with alprazolam and/or with carisoprodol, a popular “cocktail” combination in illicit use, should raise even more scrutiny with a pharmacist.

Prof. Doering will discuss certain patterns or circumstances that are consistent with drug diversion schemes that, in his opinion, a diligent pharmacist can observe, as well as the techniques that help the pharmacist detect drug diversion. Examples of such patterns or circumstances include, but are not limited to, patients who pay with cash, patients who are prescribed large quantities of controlled substances, patients who share the same address, patients who are prescribed the same numbers and types or combinations of drugs, and patients who live a distance from the prescribing practitioner

and/or pharmacy, including out-of-state patients and/or practitioners. His testimony will also cover the criteria appearing in the 2010 Edition of the Drug Enforcement Administration's Pharmacist's Manual, which provided guidance to pharmacists of indicators that a prescription was not issued for a legitimate medical purpose. Prof. Doering will testify that when taken together these "red flags" create enough suspicion that the reasonable and prudent pharmacist would refuse to fill the prescriptions.

Additionally, Prof. Doering will testify about the information he was provided by the DEA to review and analyze concerning Walgreens #03629. This information included, but is not limited to: Walgreens #03629's dispensing log, copies of prescriptions and prescription labels for Schedule II controlled substances dispensed by Walgreens #03629.

Prof. Doering will testify that based on his education, training, and experience as a pharmacist, his review and analysis of the DEA information he received shows that dispensing pharmacists at Walgreens #03629 ignored "red flags" of drug diversion or abuse and filled prescriptions that were issued outside the usual course of medical practice. He will testify that some, but not all red flags can be resolved by a pharmacist. In those instances when red flags are unresolvable, a reasonable pharmacist exercising due care would refuse to fill the prescription.

Prof. Doering will discuss his analysis of Walgreens #03629's controlled substance dispensing between January 1, 2010 and April 4, 2012. He will testify that while the number of dosage units ordered by a pharmacy does not confirm illegal activity, the larger the number of dosage units ordered and dispensed, the more suspicion is aroused. He will testify that the sheer number of controlled substance prescriptions

filled per day can be an indicator that something might be awry. Prof. Doering will discuss the increase in Walgreens #03629's average daily dispensing of controlled substances. Prof. Doering will testify that a pharmacy such as Walgreens #03629 would have expected its customer base to reach a plateau. Any drastic change in volume should cause a pharmacy to step back and figure out why. Professor Doering will testify that the rise oxycodone dispensing by Walgreens #03629 in 2010-2011, coincides with the change in Florida law, which restricted controlled substance dispensing by practitioners.

Professor Doering will testify about various other categories of red flags that appear in the dispensing logs of Walgreens #03629, including the pharmacy's filling of prescriptions for physicians (i.e., Dr. Reppy) who issue an unusually large percentage of their total prescriptions for the aforementioned drug cocktail (oxycodone, alprazolam and Soma)⁶ and customers traveling from distances over 50 miles away to have their prescriptions filled. Prof. Doering will cite as a further example the prescription forgery incident involving James McCune and how the red flags presented by that incident were not resolved by Walgreens #03629 before the pharmacy filled controlled substances prescriptions for Mr. McCune.

V. PROPOSED DOCUMENTS

1. Facsimile of DEA Certificate of Registration (attached).
2. Certified registration history for Walgreens #03629 (two pages).
3. Certified registration histories – Drs. Abaunza, Reppy, Wayne, Legowick, Wolff, McNichol and Glusman (14 pages).
4. Administrative MOA dated April 7, 2011 (seven pages).

⁶ See proposed testimony of Investigator Flagg outlined above concerning Walgreen's #03629's filling of "drug cocktail" prescriptions issued by Dr. Reppy.

5. ARCOS Report of Respondent's Oxycodone Purchases, 2006-2012
6. Printout of prescriptions filled by Walgreens #03629 (140 pages).
7. Pasco County Sheriff's Office Incident Report for James McCune (eight pages).
Prescriptions filled for James McCune (10 pages).
8. Prescription printout for James McCune (two pages).
9. Copy of prescription issued by Dr. Reppy on November 2, 2011 and filled by Walgreens #03629 (one page).
10. Copy of prescription issued by Dr. Pritchard on November 3, 2011 (one page).
11. Copy of dispensing label dated November 3, 2011 for 60 dosage units of oxycodone (listing Dr. Reppy as prescribing physician) (one page).
12. Dispensing log of Walgreens #03629's central filled prescriptions.
13. Copies of 25 randomly selected prescriptions (re: central fill prescriptions) (25 pages).
14. CV- Mary E. Chmielewski Ph.D.
15. Charts: Comparison of Total Dosages Oxycodone by Year - Walgreens #03629
16. CV – Professor Paul Doering, M.S.
17. Report - Professor Paul Doering, M.S.

VI. OTHER MATTERS WHICH MAY AID IN THE EXPEDITIOUS DISPOSITION OF THE HEARING

- a. The Government reserves the opportunity to amend its instant pleading at a time and date specified by the presiding Administrative Law Judge;
- b. The Government requests the issuance of a protective order to prevent disclosure of the identities of Walgreens #03629's customers wherever such names and records are used in this proceeding;

- c. The Government requests that due to the location of its witnesses, the Respondent, and counsel(s) for the Walgreens #03629, the hearing be held at the DEA Hearing Facility (DEAHF) located at 1550 Crystal Drive, Suite 901, Arlington, Virginia.
- d. The Government incorporates by reference its statement regarding consolidation and *res judicata*.

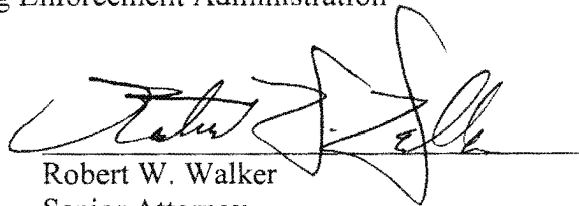
ESTIMATED TIME FOR PRESENTATION OF THE GOVERNMENT'S CASE

Three to four business days, exclusive of cross-examination and rebuttal.

Respectfully submitted,

UNITED STATES DEPARTMENT OF JUSTICE
Drug Enforcement Administration

By:



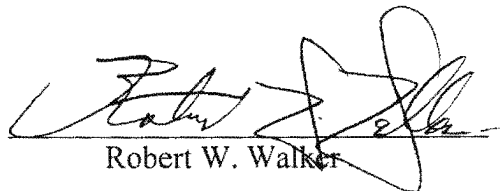
Robert W. Walker
Senior Attorney
Drug Enforcement Administration
Office of Chief Counsel
8701 Morrisette, Drive
Springfield, Virginia 22152

Attachment

CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the foregoing was this day sent via facsimile with a second copy placed in the United States Mail addressed to counsel for the Respondents, Phillip J. Perry, Esq., Nathan H. Selzer, Esq., and Allen M. Gardner, Esq., Lantham & Watkins, LLP, 55 Eleventh Street, NW, Suite 1000, Washington, D.C. 20004.

This ninth day of January 2013.



Robert W. Walker

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BW4713992	05-31-2013	\$551

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3 3N,4,5	CHAIN PHARMACY	05-12-2010

WALGREEN CO.
DBA: WALGREENS # 03629
12028 MAJESTIC BLVD.
HUDSON, FL 34667

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C. 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (05/04)

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UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

In the Matter of

Walgreen Co.
d/b/a Walgreens #04727

Docket No. 13-10

CHIEF ADMINISTRATIVE LAW JUDGE
JOHN J. MULROONEY, II

**PREHEARING STATEMENT ON BEHALF OF
THE GOVERNMENT**

Michelle F. Gillice
Scott Lawson
Attorneys
Diversion and Regulatory Litigation
Office of Chief Counsel
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, Virginia 22152
(202) 307-8010 (office)
(202) 307-4946 (facsimile)

Dated: January 9, 2013

Pursuant to the December 31, 2012 Orders for Prehearing Statements, the United States Department of Justice, Drug Enforcement Administration (DEA or Government), hereby submits its Prehearing Statement.

I. ISSUE

Whether DEA should revoke DEA Certificate of Registration BW6561270 issued to Walgreen Co. 04727 (“Respondent”), pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f) and deny any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. § 823(f).

II. REQUESTED RELIEF

The Government requests a recommended ruling by the Administrative Law Judge favorable to the Government’s contention that the Respondent’s Certificate of Registration BW6561270 should be revoked and any pending application for renewal or modification of such registration be denied.

III. PROPOSED STIPULATIONS OF FACT¹

1. Respondent is registered with DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA registration number BW6561270 at 4950 South U.S. Highway 1, Fort Pierce, Florida 34952. DEA registration BW6561270 expires by its terms on May 31, 2013.
2. Respondent has been licensed by the Florida Department of Health as a pharmacy under license number PH16392 since October 22, 1999.
3. Oxycodone is a Schedule II controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(13).
4. Alprazolam is a Schedule IV controlled substance pursuant to

¹ The Government anticipates discussing additional stipulations with Respondent.

21 C.F.R. § 1308.14(c)(1).

5. Soma is a brand name for carisoprodol, a drug typically used legitimately as a muscle relaxant. While carisoprodol was not a controlled drug prior to January 2012, it has nevertheless been a highly abused pharmaceutical agent, particularly when used in combination with certain narcotic and benzodiazepine drugs. Effective January 11, 2012, carisoprodol was placed in Schedule IV as a controlled substance pursuant to 21 C.F.R. § 1308.14.

6. Respondent is in Walgreen Co.'s Pharmacy District 112.

7. The driving distance between Respondent and the office of Dr. Charles Kessler located at 660 North State Road 7, Plantation, Florida 33317 is approximately 99 miles or an approximately one hour and forty-five minute drive.

8. The driving distance between Respondent and the office Dr. John Carrozzella located at 2921-A Vineland Road, Kissimmee, Florida 34746 is approximately 109 miles or an approximately one hour and fifty minute drive.

9. The driving distance between Respondent and the office of Dr. Ralph Miniet located at 935 Intercoastal Drive, Fort Lauderdale, Florida 33304 is approximately 98 miles or an approximately two hour drive.

10. The driving distance between Respondent and the office of Dr. Alexandra Taylor located at 660 Linton Boulevard, Del Ray Beach, Florida 33444 is approximately 72 miles or an approximately one hour drive.

IV. PROPOSED WITNESSES²

1. Susan Langston
Diversion Program Manager
DEA Miami Field Division
2100 North Commerce Parkway
Weston, Florida 33326
2. Gayle Lane
Diversion Group Supervisor
DEA Miami Field Division
2100 North Commerce Parkway
Weston, Florida 33326
3. Diversion Investigator Linda Stocum (or Group Supervisor Susan Slkyer)
DEA Orlando District Office
300 International Parkway, Suite 424
Heathrow, Florida 32746
4. Dianne Williams or Allison King
Diversion Investigator
DEA Miami Field Division
2100 North Commerce Parkway
Weston, Florida 33326
5. Mary E. Chmielewski, Ph.D.
Senior Personnel Psychologist
Research & Analysis (HRN), Human Resources Division
Drug Enforcement Administration
600 Army-Navy Drive, W-3114-4
Arlington, VA 22202
6. George Corripio
Pharmacist
Walgreen Co. Store # 5079
2423 Orange Avenue
Fort Pierce, Florida
7. Andrea Cohen
Pharmacy Manager, Store #5335
Walgreen Co.
7620 South U.S. Highway 1
Port St. Lucie, Florida 34952

² In addition to the witnesses identified below, DEA reserves the right to call any of the witnesses listed by Respondent on matters identified by Respondent.

8. Melissa Kayes
Pharmacy Technician, Store 04727
Walgreen Co.
4950 South U.S. Highway 1
Fort Pierce, Florida 34952
9. Joseph Berdie
Assistant Store Manager, Store 04727
Walgreen Co.
4950 South U.S. Highway 1
Fort Pierce, Florida 34952
10. Wesley Rohn
Pharmacy District Supervisor, Palm Beach North
Walgreen Co.
901 Northpoint Parkway, Suite 105
West Palm Beach, Florida 33407
11. Ed Svihra, RPH, CHC
Director, HealthCare Loss Prevention
1411 Lake Cook Road, MS #413
Deerfield, Illinois 60015
12. Doug Lemmons
Director, Divisional Loss Prevention Operations
Walgreen Co.
200 Wilmot Road, 2nd Floor
Deerfield, Illinois, 60015
13. Ed Lanzaletti
Market Loss Prevention Director
Walgreen Co.
1411 Lake Cook Road, 4th Floor
Deerfield, Illinois 60015
14. Paul L. Doering, M.S.
Distinguished Service Professor of Pharmacy Practice, Emeritus
College of Pharmacy
University of Florida
101 South Newell Drive
HPNP Bldg 212
Room 3307
Gainesville, Florida 32611

V. SUMMARY OF TESTIMONY

1. Susan Langston, Diversion Program Manager (“DPM”), Miami Field Division³

DPM Langston will testify to her background, education and training as a DEA Diversion Investigator, Diversion Group Supervisor, and Diversion Program Manager. DPM Langston will testify about the problem of prescription painkiller diversion and abuse in Florida and the proliferation of “pill mills” employing unscrupulous doctors who prescribe controlled substances outside the usual course of professional practice or for other than legitimate medical purposes. DPM Langston will testify that since at least 2009, the State of Florida has been epicenter of a notorious, well-documented epidemic of prescription drug abuse. The controlled substances most commonly associated with this epidemic are Schedule II pain relievers such as oxycodone; Schedule IV benzodiazepines, such as alprazolam; and Schedule IV muscle relaxers, such as carisoprodol.

DPM Langston will testify that in response the prescription pill epidemic, in 2010, the Florida legislature passed a law that restricted the ability of pain clinics to dispense controlled substances on site. DPM Langston will testify that once illicit prescriptions could not be filled at the pain clinic, pain clinic patients had to go to pharmacies to have their prescriptions filled. DPM Langston will testify that with the new law, came a wave of new pharmacy applicants for DEA registrations.

DPM Langston will testify that upon receiving applications from retail pharmacy owners in South Florida, DEA regularly conducts pre-registration interviews to discuss pharmaceutical drug diversion. In June 2011, Walgreens Co. submitted an application

³ In the event DPM Langston is unable to testify, GS Lane will offer the proposed testimony set forth below.

for a new pharmacy DEA registration in Miami. In response to Walgreen's new pharmacy application, DEA scheduled a meeting with Walgreens pharmacy representatives on August 19, 2011. DPM Langston will testify that in preparation for the meeting, DEA conducted a search of Walgreens Florida pharmacies' oxycodone purchases through DEA's Automation of Reports and Consolidated Orders System (ARCOS) which revealed that Respondent had significantly increased its oxycodone purchases between 2009 and 2011. DPM Langston will introduce an ARCOS report which shows that in 2009, Respondent had purchased a total of approximately 153,000 dosage units of oxycodone. In 2010, Respondent increased its purchases to 494,300 in 2010.⁴ DPM Langston will introduce a chart prepared for the meeting with Walgreens entitled "2010 Top 100 Florida Walgreens Pharmacy Buyers of Oxycodone." The chart shows that by July 31, 2011, in just seven months, Respondent surpassed its 2010 oxycodone purchases, having purchased 781,000 dosage units of oxycodone. DPM Langston will testify that such a dramatic increase in oxycodone purchases is an indication to DEA investigators that pharmaceutical diversion might be occurring and, coupled with the timing of the state law changes regarding pill mill dispensing, should have been an indication or "red flag" to Respondent that it was likely dispensing oxycodone pursuant to illegitimate prescriptions.

DPM Langston will testify that at the August 19, 2011 meeting, DEA investigators met with Walgreen Co. officials to discuss Walgreens' oxycodone sales in Florida and oxycodone diversion in Florida. Present on behalf of Walgreen Co. were Dwayne Pinon (corporate in-house counsel), Ed Forbes (Market Loss Prevention

⁴ A more recent compilation from ARCOS indicates Respondent purchased approximately 507,100 dosage units of oxycodone in 2010.

Director), Wesley Rohn (Pharmacy District Supervisor), Joan Bustelo (Pharmacy District Supervisor), Anne-Marie Aldrick (Pharmacy District Supervisor), Cesar Cedenio (Pharmacy District Supervisor), Lakeisha Axem (Pharmacy Supervisor), Sandra Vazquesz (Pharmacy Supervisor), and Susan Thompson (Loss Prevention Manager).

DPM Langston will testify that she and Group Supervisor (GS) Gayle Lane discussed in detail suspicious activity or “red flags” indicating that a controlled substance prescription may have come from a rogue pain management clinic, may not have been issued for a legitimate medical purpose, and/or may have been issued outside the usual course of professional practice. DPM Langston will testify that she and GS Lane identified suspicious activity or red flags related to customers indicating a risk of diversion. Such red flags included the following: people from out-of-state using questionable Florida Identification Cards, groups of patients with the same prescriptions for the more common drugs of abuse (typically oxycodone 30mg, oxycodone 15mg, Alprazolam 2mg and Soma, and one or two non-controlled prescriptions), groups of patients receiving the same prescriptions and same diagnosis, patients between 22 and 45 years old, patients traveling significant distances to the pharmacy and/or to the pain management physician, and patients paying with cash. DPM Langston will testify that patients paying with non-insurance discount cards to pay for controlled substance prescriptions are considered the equivalent of cash payments.

DPM Langston will testify that DEA also discussed physician red flags or suspicious conduct indicating the prescriptions were not issued for legitimate medical purposes or were issued outside the usual course of professional practice including: doctors writing prescriptions for the same common drugs of abuse, doctors using the same diagnosis for multiple prescriptions, and doctors whose specialties are unrelated to

pain management (e.g., obstetrics, pediatrics, or ophthalmology) prescribing large quantities of Schedule II controlled substances.

DPM Langston will testify that she and GS Lane informed Walgreens representatives of information compiled by ARCOS pertaining to Respondent and other Walgreens pharmacies' purchases of oxycodone. DPM Langston will testify that Walgreens representatives were told that the average US pharmacy purchased 69,500 dosage units of oxycodone in 2010, whereas the average Florida pharmacy purchased 134,000 dosage units of oxycodone in 2010. DPM Langston will testify that the summary chart entitled "2010 Top 100 Florida Walgreens Pharmacy Buyers of Oxycodone" was discussed at the meeting and provided to Walgreens official Dwayne Pinon. DPM Langston will testify that Walgreens representatives were told that all of its pharmacies identified on the first page of the chart had, in the first seven months of 2011, ordered more than double the amount of oxycodone purchased by the average Florida pharmacy in 2010. Respondent was identified on the first page of the chart as having purchased 781,000 dosage units of oxycodone in the first seven months of 2011 and ranked #39 in the US for top purchasers of oxycodone. The ARCOS report will show that by the end of 2011, Respondent's oxycodone purchases increased to approximately 1,192,000 dosage units.

2. Gayle Lane, Group Supervisor ("GS"), Miami Field Division⁵

Following testimony regarding her experience and qualifications as a Diversion Group Supervisor, GS Lane will testify to the background of the investigation into

⁵ GS Lane may testify to portions of DPM Langston's testimony, in lieu of DPM Langston, as outlined above.

Respondent, which stemmed from Respondent and other Walgreens pharmacies' dramatic spike in oxycodone purchases.

GS Lane will testify that on August 19, 2011, DEA met with Walgreens representatives. GS Lane will testify that she and DPM Langston advised Walgreens of customer and physician specific red flags to look for prior to dispensing prescriptions for controlled substances. These red flags pertained to both patient and physician conduct, including physicians prescribing the same commonly abused controlled substances, utilizing the same diagnosis, not certified in pain management and/or practicing outside their specialty.

GS Lane will testify that on April 4, 2012, an Administrative Inspection Warrant (AIW) was executed at Walgreens # 04727. Pursuant to the AIW, investigators obtained inventory records, prescriptions for all Schedule II controlled substances, prescription labels for all dispensed Schedule II controlled substances, and an electronic dispensing log for all Schedule II-IV controlled substances dispensed by Respondent between January 1, 2010 and April 4, 2012.⁶ GS Lane will introduce Respondent's dispensing log and summary charts which will show that Respondent dispensed controlled substances pursuant to prescriptions that presented obvious red flags.

GS Lane will testify that Respondent's dispensing log reveals that it filled prescriptions issued by doctors who routinely prescribed oxycodone and alprazolam "cocktails", who practiced outside their specialties, who were located significant distances away from the pharmacy, and whose patients paid for their prescriptions with cash or using non-insurance discount cards.

⁶ Prescription labels are affixed to the back of the prescriptions by Respondent on date of dispensing.

GS Lane will testify that between January 1, 2010 and March 21, 2012, Respondent filled 723 controlled substance prescriptions issued by Dr. Kenneth Pearlberg, an ophthalmologist⁷, located approximately 69 miles from Respondent in Boca Raton. Dr. Pearlberg surrendered his DEA registration for cause on March 21, 2012. Through her testimony and use of a chart that she prepared summarizing data from Respondent's dispensing log, GS Lane will show that approximately 73% of Dr. Pearlberg's prescriptions were for oxycodone and alprazolam cocktails. Approximately 50% of Dr. Pearlberg's patients paid for these prescriptions with cash or using non-insurance discount cards such as the WellCard, Familywise Card, Age & Agility Card, and Walgreens Card ("WCard").

GS Lane will testify that between January 1, 2010 and April 2012, Respondent dispensed at least 657 controlled substance prescriptions issued by Dr. Alexandra Taylor, certified in obstetrics and gynecology⁸, located in Del Ray Beach, Florida. GS Lane will introduce a chart she prepared summarizing data from Respondent's dispensing log, showing that approximately 78% of Dr. Taylor's prescriptions were for oxycodone and alprazolam cocktails.

GS Lane will testify that between January 1, 2010 and April 2012, Respondent dispensed at least 745 controlled substance prescriptions issued by Dr. Ralph Miniet, a pediatrics specialist⁹, located approximately 90 miles from Respondent in Fort Lauderdale, of which 73% of the prescriptions were for oxycodone and alprazolam cocktails. GS Lane will testify that approximately 86% of Dr. Miniet's patients paid for

⁷ GS Lane will introduce documents from the Florida Department of Health's medical license verification website showing that Dr. Pearlberg is an ophthalmologist.

⁸ GS Lane will introduce documents from the Florida Department of Health's medical license verification website showing that Dr. Taylor is certified in obstetrics and gynecology.

⁹ GS Lane will introduce documents from the Florida Department of Health's medical license verification website showing that Dr. Miniet specializes in pediatrics.

these prescriptions with cash or non-insurance discount cards. GS Lane will introduce prescription copies, prescription labels and a summary chart she prepared from Respondent's dispensing log regarding customers who were prescribed oxycodone by Dr. Miniet dispensed by Respondent on August 10, 2011 and October 4, 2011.¹⁰

GS Lane will testify about and introduce a sampling of 20 prescriptions for oxycodone dispensed by Respondent between March 2011 and December of 2011 despite its own pharmacists' warnings or noted "red flags" concerning the physicians. These warnings appear on the prescription labels under the physician's name as well as in Respondent's dispensing log. The physicians and the warnings on the prescription labels for filled oxycodone prescriptions include the following: Ramiro Abaunza, M.D., "DO NOT FILL CONTROL. MID UNDER INVESTIGAT"; Dr. Astrid Febre, "FAKE CII, VERIFY ALL, CANDY DR CHECK FOR"; John Wolf, M.D., "DO NOT FILL ANY CII"; Ronald Heromin, M.D, "DO NOT FILL CONTROLS"; and Barry Schultz, M.D.; "MD HAS HX OVERPRESCRIBE".¹¹

GS Lane will introduce an Emergency Suspension Order from the Florida Department of Health showing that on April 13, 2011, it suspended the medical license of Barry Schultz, M.D. for excessive and inappropriate prescribing of controlled substances. GS Lane will introduce an excerpt from Respondent's dispensing log showing that it dispensed oxycodone pursuant to Dr. Schultz's prescriptions after his medical license was suspended on April 18 and 19, 2011. GS Lane will also discuss the pharmacist's notes in the dispensing log on the aforementioned dates which state "LIC. SUSP'D 4.14.11." GS Lane will introduce prescriptions issued by Dr. Schultz and Respondent's prescription

¹⁰ The red flags associated with Dr. Miniet's prescriptions dispenses on these dates will be expanded upon through the proposed expert testimony of Paul Doering, M.S.

¹¹ The red flags associated with these prescriptions will be expanded upon through the expert testimony Paul Doering, M.S.

labels showing that it dispenses oxycodone pursuant to Dr. Schultz's prescriptions on April 18 and 19, 2011. The April 19, 2011 prescription label contains the following language under Dr. Schultz's name "13550 JOG RD.....LIC SUSP'D 4.14.11."

Through the testimony of GS Lane, the Government will introduce prescriptions, prescription labels, and a summary chart showing that Respondent filled oxycodone and alprazolam cocktail prescriptions on several occasions for a group of customers sharing the same addresses, prescribed by the same out town physician on May 4, June 1, June 28, July 26 and September 21, 2011.¹²

Through the testimony GS Lane, the Government will introduce a letter she obtained from St. Lucie County Sherriff's Office dated October 28, 2011 from Sherriff Ken Mascara to Respondent requesting Respondent's "*help in dealing the with prescription painkiller epidemic*" in St. Lucie County and Florida by "*closely scrutinizing*" prescriptions for Schedule II narcotics, written by out-of-town physicians and/or written for out-of town individuals.

GS Lane will testify that during the execution of the AIW on April 4, 2012, she spoke with Wesley Rohn, the District Pharmacy Supervisor for Palm Beach North. GS Lane recalled that Wesley Rohn attended the August 19, 2011 meeting with DEA Diversion management and investigators. GS Lane will testify that Mr. Rohn reviewed the AIW and then pointed to it and said they "don't do this anymore", and that they stopped "last month". When GS Lane asked Mr. Rohn why Respondent did not not take action after meeting with DEA eight months earlier, Mr. Rohn did not respond.

GS Lane will testify that on August 23, 2012, she and other DEA investigators

¹² Red flags of diversion and abuse associated with the prescriptions dispensed on these dates will be expanded upon through the expert testimony Paul Doering, M.S.

and DEA Chief Counsel attorneys interviewed Walgreens pharmacist George Corripio. Mr. Corripio stated that he was transferred from Walgreens #5079 in Fort Pierce to Respondent for a period of about six months in 2010/2011.¹³ GS Lane will testify that Mr. Corripio said that as soon as he was transferred to the store he immediately wanted to leave due to the heavy oxycodone traffic. Mr. Corripio said that “80% of clientele was oxy” and that he thought it was “terrible.” Mr. Corripio said the oxycodone prescriptions were mainly for young people with diagnoses of lower back pain, that the pain clinics all gave the same lower back pain diagnosis for patients, and that the customers appeared to be under the influence of controlled substances. Mr. Corripio said that “nothing felt right” and he did not think the customers or the doctors were being truthful about the prescriptions.

Mr. Corripio stated that Respondent’s Pharmacy Manager, Andrea Cohen, tried to alleviate his concerns regarding filling the oxycodone prescriptions. She told him to call the doctor, write a diagnosis code, and then “we will be fine.” Mr. Corripio said he did not believe the diagnosis codes fit the customers. Mr. Corripio said he would fill one person’s prescriptions, and immediately three to four other customers would come to the pharmacy with similar prescriptions. Moreover, when he would call the doctor’s office, some person at the clinic who was not the doctor would rattle off the same diagnosis for all the patients. Mr. Corripio said Ms. Cohen filled the Schedule II narcotic prescriptions that he felt uncomfortable filling. Mr. Corripio said testify Ms. Cohen also filled the prescriptions that the floater pharmacists would not fill. Mr. Corripio told DEA investigators that when he refused to fill a prescription, customers would get angry and ask when the ‘lady’ pharmacist was coming back.

¹³ At the time of the interview, Mr. Corripio was working at Walgreens #5079 in Fort Pierce, Florida.

3. Mary Chmielewski, Ph.D.

Dr. Chmielewski is a Senior Personnel Psychologist who works in the Research & Analysis Group of DEA's Human Resources Division. In the course of her official duties, Dr. Chmielewski frequently performs statistical analysis and interpretation. Dr. Chmielewski will provide expert testimony regarding statistical analysis of ARCOS data related to the oxycodone purchased by Respondent between January 1, 2006 and December 31, 2011. Dr. Chmielewski will testify that the volume increase of oxycodone purchases observed over this period of time was statistically significant.

4. Linda Stocum, Diversion Investigator¹⁴

Following testimony about her experience and qualifications as a Diversion Investigator DI Stocum, will testify about the investigation into controlled substances filled by Walgreen Co.'s central fill facility located in Orlando, Florida. As part of the existing investigation into several Florida Walgreens pharmacies, including Respondent, and the Walgreens Distribution Center in Jupiter, Florida, DEA obtained hard copies of prescriptions filled at those pharmacies between January 2010 and April 2012. DEA also obtained controlled substances dispensing logs from the pharmacies. Based on a review of the documents obtained from the AIWs as well as the continuing DEA investigation into Walgreens, DEA requested copies of all controlled substance prescriptions filled by the Walgreens Mail Order facility out of Orlando, Florida. DEA obtained copies of all prescriptions filled by the facility between January 1, 2010 and April 2012.

After a review of the Mail Order prescriptions and a comparison to ARCOS information on controlled substance purchases made under the Mail Order DEA registration, DEA contacted the facility to inquire about large discrepancies between

¹⁴ In the event DI Stocum is unable to testify, GS Susan Silkyer will offer the proposed testimony below.

controlled substances ordered and prescriptions filled. At this time, Walgreens informed DEA that in addition to operating a mail order facility, Walgreens also runs their central pharmacy operations (“Central Fill”) out of the same Orlando facility. DI Stocum will explain how the Central Fill facility operates: namely, that a Walgreens pharmacy will send certain prescriptions to the facility to be filled, and the facility will then send the filled prescription back to the pharmacy for dispensing to the ultimate customer.

DI Stocum and DI Deborah George conducted an on-site visit to the Central Fill facility on June 19 and June 21, 2012. DI Stocum will testify about the site visit and what she learned about the facility and operations at that time. She will testify that the Walgreens Central Fill staff provided verbal explanations of the operations conducted at the facility, but were unable to provide DEA with documentation regarding filled prescriptions.

DI Stocum will introduce an administrative subpoena issued on July 27, 2012 to Walgreen Co. for dispensing records from Central Fill. DI Stocum will testify that pursuant to an administrative subpoena, on October 25, 2012, Walgreen Co. produced dispensing log spreadsheets from Central Fill. DI Stocum will introduce a summary spreadsheet of Central Fill’s prescriptions dispensed for Respondent between January 1, 2010 and June 12, 2012, indicating that Central Fill dispensed 648 prescriptions in Schedule III-V for Respondent.

DI Stocum will testify that pharmacies sending prescriptions to a central fill facility must notate “CENTRAL FILL” on the face of the original prescriptions as required under 21 C.F.R. § 1306.27(a)(1). DI Stocum will testify about the effect of non-compliance with this provision of the CFR; namely the complications created in

attempting to perform an audit or otherwise capture the full picture of tracking controlled substance distributions and dispensing.

5. Dianne Williams, Diversion Investigator¹⁵

Following testimony about her experience and qualifications as a Diversion Investigator, DI Williams will testify that she reviewed the Central Fill dispensing spreadsheet identifying 648 prescriptions filled for Respondent. DI Williams and DI Allison King reviewed prescription obtained pursuant to the AIW and noted that none of the prescriptions appeared to bear the notation “CENTRAL FILL”.

On October 30, 2012, DI Williams and DI King visited Respondent and presented a Notice of Inspection to Pharmacy Manager Patrick Haro. DI Williams and DI King requested that Mr. Haro provide approximately twenty (20) controlled substances prescriptions filled for Respondent by the Central Fill. In addition, DI Williams requested copies of the computer print screen called “RX View” for each prescription. DI Williams will testify that the RX View provides an image of the prescription accompanied with the prescription and dispensing information. DI Williams will introduce copies of 20 prescriptions and accompanying RX Views for the controlled substances prescriptions filled by Central Fill that were provided by Respondent following the inspection. The documents will show that Respondent failed write “CENTRAL FILL” on the face of any of the original prescriptions.

DI Williams will testify that per her request, Pharmacist Haro provided twenty (20) CPO FILL INTERSTORE TRANSFER CLAIM forms to support Respondent’s receipt of the requested prescriptions which were filled by Central Fill. The transfer claims fail to identify the prescription number, patient name or any other way for DEA to

¹⁵ In the event DI Williams is unable to testify, DI Allison King will offer the proposed testimony below.

determine which prescription goes with which transfer claim. On eleven of the twenty Central Fill transfer claims, Respondent failed to record the date of receipt and the pharmacy employee accepting delivery of the filled prescriptions.

6. George Corripio, Walgreens Pharmacist

George Corripio will testify that he has been a pharmacist for 31 years and is a staff pharmacist at Walgreens 05079. Mr. Corripio was transferred to Respondent for a period of approximately six months in 2010/2011. He will testify that Walgreens 04727 had “heavy CII traffic” and after filling a few oxycodone prescriptions, he refused to fill more. Mr. Corripio will testify that “80% of clientele was oxy” and that he thought it was “terrible.” Mr. Corripio will testify that there was a huge difference in clientele between Walgreens 04727 and his former pharmacy (Walgreens 05079) even though they were less than five miles apart. Mr. Corripio will testify that the oxycodone prescriptions were mainly for young people with diagnoses of lower back pain, that the pain clinics all gave the same lower back pain diagnosis for patients, that the customers appeared to be under the influence of controlled substances. Mr. Corripio will testify that “nothing felt right” and he did not think the customers or the doctors were being truthful about the prescriptions.

Mr. Corripio will testify that the Respondent’s Pharmacy Manager, Andrea Cohen, tried to alleviate his concerns regarding filling oxycodone prescriptions. She told him to write a diagnosis code, call the doctor and then “we will be fine.” However, Mr. Corripio did not believe the diagnosis codes fit the customers. He will testify that if he would fill one person’s prescriptions, immediately three to four other customers would come to the pharmacy with similar prescriptions. Moreover, when he would call the doctor’s office, some person at the clinic who was not the doctor would rattle of the same

diagnosis for all the patients. Eventually, Andrea Cohen told Mr. Corripio that she would fill the Schedule II narcotic prescriptions. Mr. Corripio will testify Andrea Cohen also filled the oxycodone prescriptions that Respondent's floater pharmacists would not fill. He will further testify that when he refused to fill a prescription, customers would get angry and ask when the 'lady' pharmacist was coming back.

Mr. Corripio will testify that oxycodone dispensing at Walgreens 04727 was "out of control" and he told Fort Pierce police that he needed help. He said pharmacy personnel were aware of the problem, especially after receiving a letter from the St. Lucie County Sheriff's Office.

Mr. Corripio will testify that Andrea Cohen would almost always ask the "Oxy customers" if they would like to purchase the Walgreens cash discount card. Mr. Corripio will testify about the purpose of the cash discount cards and how it used with pharmacy prescriptions.

7. Melissa Kayes, Pharmacy Technician

Ms. Kayes will be asked to testify about oxycodone prescriptions filled while she was under the supervision of pharmacy manager Andrea Cohen. She will be asked to testify about red flags for diversion and abuse and how she would try to resolve those red flags. Ms. Kayes will be asked to testify about any guidance she received from Andrea Cohen on how to identify and handle suspicious prescriptions for controlled substances. Ms. Kayes will be asked to testify about the practice of refusing to fill prescriptions for controlled substances under her supervisor Andrea Cohen. Ms. Kayes will be asked to testify about specific oxycodone and alprazolam prescriptions she dispensed on May 4, 2011, June 28, 2011, and July 21, 2011.

8. Andrea Cohen, Pharmacy Manager

Ms. Cohen will be asked to testify about her experience as pharmacy manager and her role in dispensing oxycodone and other controlled substances as well as her supervision of pharmacists and pharmacy technicians. She will be asked about the explosive growth of oxycodone ordering and dispensing while she was pharmacy manager at Respondent's location.

Ms. Cohen will be asked about dispensing guidelines and practices while she was the manager at Respondent's location. Ms. Cohen will be asked about red flags for diversion and abuse and how she resolved those red flags prior to dispensing. She will be asked about guidance she received with respect to the growth of oxycodone customers in 2010 and 2011 and dispensing guidance from her supervisors.

She will be asked about the guidance she provided to other pharmacy staff on how to resolve red flags pertaining to controlled substance prescriptions. Ms. Cohen will be asked about filling oxycodone prescriptions for other pharmacists who declined to fill prescriptions. Ms. Cohen will be asked about specific prescriptions she dispensed and that were dispensed by other pharmacists and/or technicians under her supervision on May 4, 2011 and June 28, 2011 and July 26, 2011.

Ms. Cohen will be asked about any bonuses and salary raises while at Respondent's location. Ms. Cohen will be asked to testify about the circumstances concerning her transfer from Respondent to another Walgreen Co. pharmacy in Port Saint Lucie, Florida.

9. Joseph Berdie, Assistant Store Manager

Mr. Berdie will be asked about the oxycodone customer traffic at Respondent's location between 2010 through 2011. Mr. Berdie will be asked about an email he sent to

Wesley Rohn on January 5, 2011 entitled “C2 ID requirements” seeking advice about dispensing an oxycodone prescription to a customer without a proper ID. He will be asked to testify as to the direction he received from Wesley Rohn and/or other management. Mr. Berdie will be asked to testify about the guidance he received from Andrea Cohen, Wesley Rohn and other management on how to handle prescriptions or customers that present red flags for diversion and abuse. Mr. Berdie will be asked to testify about the controlled substances dispensing practices of other pharmacists and technicians that he observed.

10. Wesley Rohn, Pharmacy District Supervisor

Mr. Rohn will be asked to testify about inquiring about ordering a new CII safe for Respondent in December 2010. Mr. Rohn will be asked to testify about an email he sent to his district pharmacies on November 23, 2010 entitled “Professionalism and CII’s” with instructions to “**PLEASE POST ON CII CABINET**”. Mr. Rohn will be asked to testify about his response to concerns raised by Respondent’s assistant store manager Joseph Berdie about concerns with dispensing controlled substances for a customer without a valid ID. He will be asked to discuss his response to concerns raised by Respondent’s Store Manager Lori Bellino about Andrea Cohen and “C2” scripts. He will be asked to testify about guidance he emailed to his district following the August 22, 2011 meeting with DEA.

11. Edward Svihra, RPH, Health Care Loss Prevention Director

Mr. Svihra will be asked to testify about his Florida pharmacy “pain management” visits in early 2012 with Doug Lemmons and specifically, his visit to Respondent’s store. Mr. Svihra will be asked to testify about concerns he, Doug Lemmons and Ken Amos discussed in January 2011 regarding Respondent’s oxycodone

dispensing. Mr. Svihra will also be asked to testify about a pharmacist's hotline complaint received in 2011 regarding Respondent's pharmacists being asked to fill prescriptions they were uncomfortable filling.

12. Doug Lemmons, Loss Prevention Operations Director

Mr. Lemmons will be asked to testify his Florida pharmacy "pain management" visits in early 2012 with Edward Svihra, and specifically, his visit to Respondent's store in 2012. Mr. Lemmons will be asked to testify about concerns identified in January 2011 and discussed with Mr. Svihra and Ken Amos regarding Respondent's oxycodone dispensing.

13. Edward J. Lanzetti, Market Loss Prevention Director

Mr. Lanzetti will be asked about his role as a Market Loss Prevention Director and its relation to Respondent and other Walgreen's pharmacies' dispensing of controlled substances. He will be asked to testify about an email he sent dated May 19, 2011 in which he attached a "Special Focus on Profit for Florida Market" regarding Walgreens "CII" dispensing in Florida. He will be asked to testify about the red flags identified in the focus report. He will be asked to testify about his email dated June 21, 2011 raising concerns about the "Focus on Compliance" program (renamed from "Focus on Profit.")

14. Paul Doering, M.S.

Professor Doering will testify regarding his education, background, training, and experience as a pharmacist. In this regard, among other matters, Prof. Doering will testify that he (1) is a registered pharmacist in the states of Florida and North Carolina, (2) is certified as a Consultant Pharmacist in Florida, (3) previously practiced in the community pharmacy setting, (4) has been a professor at the University of Florida's

School of Pharmacy for the past 35 years, (5) currently serves at the University of Florida's College of Pharmacy as Distinguished Service Professor of Pharmacy Practice, Emeritus, and (6) for 28 years was either Director or Co-Director of the University of Florida's Drug Information and Pharmacy Resource Center, a telephone access service through which health professionals can obtain information about drugs or drug therapy. Prof. Doering will further testify about his experiences serving as an expert consultant and witness in a number of criminal, civil, and administrative proceedings. Prof. Doering will provide expert witness testimony as detailed below.

Prof. Doering will testify about the education and training pharmacists receive in pharmacy school, including learning the fundamentals of both state and federal pharmacy law as it relates to the filling and dispensing of prescription drugs in general, and controlled substances in particular. He will further testify about training pharmacists receive in the application of those laws to real life situations. He also will discuss the coverage of these topics in Florida's pharmacist licensing exam.

Prof. Doering will testify about the epidemic of prescription drug diversion and abuse in the state of Florida. He will discuss the in 2011 State of Emergency declared by the Florida Surgeon General which was issued in effort to prevent the many drug overdose deaths from controlled substances. The controlled substances commonly associated with this epidemic are Schedule II pain relievers such as oxycodone; Schedule IV benzodiazepines, such as alprazolam; and Schedule IV muscle relaxers, such as carisoprodol. Prof. Doering will testify about the overdose deaths due to oxycodone and benzodiazepines identified by the 2011 Florida Medical Examiners Report. He will testify that pharmacists are in a key position to reverse the trend of this epidemic.

Prof. Doering will further testify about the pharmacist's role in the distribution of prescription drugs that are controlled substances. He will testify about the dangerous propensities of certain controlled substances, in particular opiates and opioids such as oxycodone and benzodiazepines such as diazepam (Valium) and alprazolam (Xanax). Prof Doering will testify that when controlled release opiate products are prescribed correctly, patients should not need to be on concurrent around the clock opiates for break through pain.

Prof. Doering will discuss the responsibilities of pharmacists in filling controlled substances prescriptions. Prof. Doering will testify about the review and analysis pharmacists should undertake before certifying any such prescription for release to the patient, including checking the licensing status of prescribers and evaluating whether the prescription presented to them is for a legitimate medical purpose and issued by a properly registered practitioner in the usual course of professional practice.

Moreover, Prof. Doering will testify about the "red flags," or, in other words, indicators of diversion and abuse, used by pharmacists to detect drug diversion. Because of the enormous abuse and diversion associated with oxycodone, the mere fact that an oxycodone prescription is being presented should put the pharmacist on full-alert to ensure that the prescription is valid. He will testify that oxycodone prescribed in combination with alprazolam and/or with carisoprodol, a popular "cocktail" combination in illicit use, should raise even more scrutiny with a pharmacist.

He will discuss certain patterns or circumstances that are consistent with drug diversion schemes that, in his opinion, a diligent pharmacist can observe, as well as the techniques that help the pharmacist detect drug diversion. Examples of such patterns or circumstances include, but are not limited to, patients who pay with cash, patients who

are prescribed large quantities of controlled substances, patients who share the same address, patients who are prescribed the same numbers and types or combinations of drugs, and patients who live a distance from the prescribing practitioner and/or pharmacy, including out-of-state patients and/or practitioners. His testimony also will cover the criteria appearing in the 2010 Edition of the Drug Enforcement Administration's Pharmacist's Manual, which provided guidance to pharmacists of indicators that a prescription was not issued for a legitimate medical purpose. Prof. Doering will testify that when taken together these "red flags" create enough suspicion that the reasonable and prudent pharmacist would refuse to fill the prescriptions.

Additionally, Prof. Doering will testify about the information he was provided by the DEA to review and analyze concerning Respondent. This information included, but is not limited to: Respondent's dispensing log, copies of prescriptions and prescription labels for Schedule II controlled substances dispensed by Respondent, specialty status for prescribers from the Florida Department of Health, spreadsheets for prescription dispensing activity, and copies of electronic mail messages dispatched to Respondent and other parties in the Walgreens organization.

Prof. Doering will testify that based on his education, training, and experience as a pharmacist, his review and analysis of the DEA information he received shows that Respondent's pharmacists ignored "red flags" of drug diversion or abuse and filled prescriptions that were issued outside the usual course of medical practice. He will testify that some, but not all, red flags can be resolved by a pharmacist. In those instances, when red flags are unresolvable, a reasonable pharmacist exercising due care would refuse to fill the prescription.

Prof. Doering will discuss his analysis of Respondent's controlled substance dispensing between January 1, 2010 and April 4, 2012. He will testify that while the number of dosage units ordered by a pharmacy does not confirm illegal activity, the larger the number of dosage units ordered and dispensed, the more suspicion is aroused. He will testify that the sheer number of controlled substance prescriptions filled per day can be an indicator that something might be awry. Prof. Doering will introduce a chart to illustrate the increase in Respondent's average daily dispensing of controlled substances. In the first six months of 2010, Respondent dispensed on average 35.3 controlled substance prescriptions per day. In the first six months of 2011, that number rose to an average of 72.5 prescriptions dispensed per day. For example, on June 28, 2011, Respondent filled 156 controlled substances prescriptions of which 42 prescriptions alone were for oxycodone 30mg. Prof. Doering will testify that a pharmacy that has been licensed since 1999, such as Respondent, would have expected its customer base to reach a plateau. Any drastic change in volume should cause a pharmacy to step back and figure out why. Professor Doering will testify that the rise oxycodone dispensing by Respondent in 2010-2011, coincides with the change in Florida law, which restricted controlled substance dispensing by practitioners.

Candy Doctor Prescriptions

Prof. Doering will testify about oxycodone dispensed by Respondent pursuant to prescriptions which Respondent's pharmacists noted on the prescription labels warnings about the legitimacy of the prescription and/or the prescriber. Prof. Doering will discuss the red flag notations in the dispensing log and appearing on the prescription labels. Such with warnings include: DO NOT FILL CONTROL. MD UNDER INVESTIGAT', "FAKE CII, VERIFY ALL, CANDY DR CHECK FOR", "DO NOT FILL CONTROLS", etc. Prof. Doering will

testify that despite these noted red flags that oxycodone prescriptions were illegitimate, Respondent dispensed oxycodone anyway.

Dr. Miniet's Prescriptions

Prof Doering will testify that he identified 13 high volume prescribers who make up only 0.7% of Respondent's controlled substance prescribers, but accounted for 17.7% of all controlled substances filled by Respondent. Prof. Doering will discuss Dr. Ralph Miniet (ranking #4 on the high volume prescriber chart). Dr. Ralph Miniet, a pediatrics specialist, located approximately 98 miles from Respondent in Fort Lauderdale, issued 745 prescriptions that were dispensed by Respondent. Prof Doering will testify that he analyzed two days of dispensing involving Dr. Miniet's oxycodone and alprazolam prescriptions.

Prof. Doering will testify that it is a red flag when more than one patient presents similar controlled substance prescriptions on the same day issued by the same physician. He will testify that a pharmacist should have heightened concern when seemingly unrelated persons present similar prescriptions from prescriber located far away within a short time period. Prof. Doering will introduce summary charts for two dispensing days showing prescriptions issued by Dr. Ralph Miniet. On August 10, 2011, Respondent filled 12 prescriptions for oxycodone 30mg, oxycodone /acetaminophen 10-325 mg, and alprazolam 2mg, for five patients, S.A., C.A., C.B., J.P, and R.B. The prescription labels indicate that four of the five patients had their prescriptions dispensed within the same two minute time frame. On October 4, 2011, Respondent filled 15 prescriptions for oxycodone 30 mg, oxycodone /acetaminophen 10-325 mg, alprazolam 2mg, issued by Dr. Miniet to six patients, S.A., C.A., C.B, J.P., S.M., and M.L. Prof. Doering will testify that the timing of dispensing indicates the prescriptions for each patient were filled on the

heels of the other. Prof. Doering will testify that on several of the customers' prescription labels, the pharmacist indicated that prescription could only be picked up by the patient. This indicates that a pharmacist already had some concerns about customer or the prescription. Prof. Doering will testify that on August 10 and October 4, 2011, Respondent dispensed the aforementioned prescriptions despite unresolved red flags.

1205 Seaway Drive Customers

Prof. Doering will testify that patients arriving in groups and or sharing the same address present a huge "red flag" to a pharmacist. This is because patients who learn of "pill mill" doctors in distance places from their homes will share transportation costs in traveling to those doctors and share transportation to pharmacies known to fill purported prescriptions without a hassle. Prof. Doering will discuss in detail twenty controlled substance prescriptions for oxycodone and alprazolam filled by Respondent on May 4, 2011 for 6 patients, B.A., J.B., M.H., N.C. R.O., and E.C., all of whom resided the same address, 1205 Seaway Drive, Apt. 4, Fort Pierce, Florida 34949. Additional red flags include the prescriptions being filled within minutes of each other, and that all prescriptions were issued by Dr. Charles Kessler, located approximately 99 miles away from Respondent in Plantation, Florida. Prof. Doering will testify that Respondent dispensed these controlled substance prescriptions to B.A., J.B., M.H., N.C., and E.C. in spite of unresolved red flags. He will testify that similar dispensing, despite multiple unresolved red flags, occurred with respect to these and additional patients residing at 1205 Seaway Drive, Apt. 4., or new shared addresses on June 1, 2011, June 28, 2011, July 26, 2011 and September 21, 2011.

On June 1, 2011, B.A, J.B., E.C., N.C., and R.O. presented oxycodone and alprazolam prescriptions all issued by Dr. John Carrozzella, a physician located

approximately 109 miles away from Respondent in Kissimmee, Florida. The prescription labels reveal that all five patients shared the same address at 1205 Seaway Drive Apt. 4, and all ten oxycodone prescriptions were dispensed within minutes of each other. Prof. Doering will testify Respondent dispensed these prescriptions for controlled substances despite multiple unresolved red flags.

On June 28, 2011, Respondent filled 12 controlled substance prescriptions for oxycodone and alprazolam for customers B.A., E.C., N.C. and R.O. all prescribed by Dr. John Carrozzella. The prescription labels reveal the N.C. and R.O. shared a new address at 1910 Wyoming Avenue in Fort Pierce. Additionally, Professor Doering will testify that on this date, Respondent dispensed an enormous volume of controlled substances, 155 prescriptions total.

On July 26, 2011, Respondent filled 15 controlled substances prescriptions for oxycodone and alprazolam for customers B.A., E.C., N.C., R.O., and M.H. All prescriptions were issued by Dr. John Carrozzella. All prescriptions were filled within minutes of each other. E.C. and M.H. shared the same address at 9319 Breakers Row, Fort Pierce, Florida. N.C. and R.O. shared the same address at 1910 Wyoming Avenue. Prof. Doering will testify that despite multiple unresolved red flags, Respondent dispensed controlled substances to these customers.

Prof Doering will discuss that on September 21, 2011, Respondent filled oxycodone and alprazolam prescriptions for M.H., E.C. and N.C., all prescribed by Dr. John Carrozzella. All three patients presented new Florida Identification cards picked up the same day and had changed their address from 1205 Seaway Dr. to 7500 Pensacola Road. Respondent's pharmacist handwrote concerns which identified red flags on the oxycodone prescription labels for M.H., E.C., and N.C. The pharmacist noted it was

“strange” that these three customers all picked up new Florida Identification Cards on the same day they presented their oxycodone prescriptions for filling, and the new identification cards showed they all shared the same new address. Prof. Doering will testify that these red flags were not resolved prior to Respondent dispensing controlled substances to these customers.

Unauthorized Prescriptions

Prof. Doering will testify that on several occasions, Respondent filled prescriptions by persons not authorized to prescribe controlled substances. He will testify that under Florida law, advanced registered nurse practitioners and physician assistants are not authorized to prescribe controlled substances. On at least four occasions, Respondent filled controlled substance prescriptions written by physician assistants. On at least two of those occasions, Respondent’s dispensing log showed that the physician assistant used a DEA registration assigned to a medical doctor. Prof. Doering will introduce a summary chart based on Respondent’s dispensing log showing on four occasions, Respondent dispensed controlled substances prescribed by the following physician assistants: Larry James, Michael Carpino, Peter Vo, and Jeffrey Patane. Through the testimony of Prof. Doering, the Government will introduce documentation from the Florida Department of Health showing the aforementioned individuals are licensed as physician assistants.

Prof. Doering will testify that in his opinion, Respondent’s pharmacists failed to exercise that degree of professional judgment that a reasonable and prudent pharmacist would have done in like or similar circumstances when dispensing controlled substances. He will opine that some red flags presented with prescriptions were unresolvable and that a prudent pharmacist would not have dispensed under those circumstances. He will opine

that Respondent's pharmacists failed to execute their duty to verify whether or not the large number of prescriptions written and dispensed were for a legitimate medical need and demonstrated a reckless indifference for the consequences of their actions or inactions.

VI. PROPOSED DOCUMENTS

Exhibit	Description	Approx. # Pages
1	DEA Certificate of Registration BW6561270 (attached hereto)	1
2	Walgreens Attendee List , DEA Meeting on August 19, 2011	2
3	Chart of Respondent's Oxycodone Sales & Ranking in 2010 and 2011 provided to Walgreens officials at August 19, 2011 DEA meeting	3
4	ARCOS Report of Respondent's Oxycodone Purchases, 2006-2012	5
5	Summary Chart of Respondent's Oxycodone Purchases	2
6	Curriculum Vitae of Mary E. Chmielewski, Ph.D	5
7	Copy of the Administrative Inspection Warrant dated April 3, 2012	12
8	DEA Receipt for Cash and Other Items dated April 4, 2012 identifying receipt of 4 boxes of Schedule II prescriptions	1
9	Administrative Subpoena dated March 19, 2012	1
10	Walgreens Response to Admin Subpoena dated May 4, 2012	6
11	Respondent's Controlled Substances Dispensing Log, January 2010 – April 4, 2012.	(CD ROM) 1,060
12	Florida Department of Health, Physician Profiles for physicians Alexandra Taylor M.D., Kenneth Pearlberg, M.D., and Ralph Miniet, M.D.	4
13	Summary Chart of Dr. Pearlberg's prescriptions	1
14	Summary Chart of Dr. Miniet's prescriptions	1
15	Summary Chart of Dr. Taylor's prescriptions	1
16	Dispensing Log Summary: Dr. Schultz	1
17	Florida Department of Health Emergency Suspension Order, Barry Schultz M.D., April 13, 2011	65
18	Copies of Prescriptions ¹⁶ re: Candy Drs., etc.	40

¹⁶ All copies of prescriptions identified as Exhibits include copies of the prescription label affixed to the back of the prescription by Respondent on date of dispensing.

19	Copies of Prescriptions issued by Barry Schultz M.D.	4
20	Prescription copies for B.A., J.B., E.C., N.C., M.H., and R.O. dispensed on May 4, 2011	28
21	Prescription copies for B.A., J.B., E.C., N.C., and R.O. dispensed on June 1, 2011	20
22	Prescription copies for B.A., E.C., N.C., and J.B., dispensed on June 28, 2011	16
23	Prescription copies for B.A., E.C., N.C., M.H., and R.O. dispensed on July 26, 2011	20
24	Prescription copies for B.A., J.B., M.H., E.C. and N.C. dispensed on September 21, 2011	16
25	Prescription copies for S.A., C.A., C.B., J.P., and R.B dispensed on August 10, 2011	20
26	Prescription copies for S.A., C.A., C.B., J.P., S.M., and M.L. , dispensed on October 4, 2011	22
27	St. Lucie County Sherriff Ken Mascara Letter to Respondent, dated October 28, 2011	1
28	Administrative Subpoena issued July 27, 2012	6
29	Central Fill CII Dispensing Log	196
30	Notice of Inspection, October 30, 2012	1
31	Central Fill: 20 Prescription Copies, RX View, CPO Interstore Transfer Claims	60
32	Email from Pharmacy Manager 04727 forwarding Wesley Rohn email dated November 23, 2010 re: "Professionalism and CIIs*** PLEASE POST ON CII CABINET***"	1
33	Email from Wesley Rohn dated December 2, 2010 re: "C-II Safe"	1
34	January 5, 2011 email exchange between Store 4727, Joseph Berdie, and Wes Rohn re: "C2 ID requirements?"	2
35	January 6 ,2011 email exchange between Andrea Cohen and Wesley Rohn re: " CII procedures"	1
36	Email from Ed Lanzetti dated May 19, 2011 re: "Focus on Profit for Florida Market" with Attachment	8
37	Email from Store Manager 04727dated January 12, 2011 re: "C2 Concerns"	1
38	Email chain dated January 17- 20, 2011, Subject: "Fort Pierce" (WAG00000889-0901)	13
39	Email from Wesley Rohn dated August 22, 2011 re: "DEA Meeting Best Practices"	1
40	Email dated March 22, 2012, "REQUEST REVIEW: Florida Pain Management Visits" (WAG00001638)	1
41	Curriculum Vitae of Paul L. Doering, M.S.	31
42	Chart of High Volume Prescribers	2
43	Summary Chart: Average Daily Dispensing of	1

	Controlled Substances, Six Month Increments (January 2010 – April 4, 2012)	
44	Summary Chart of Dr. Miniet's Filled Prescriptions on August 10, 2011 and October 4, 2011	2
45	Summary Chart Dispensing to 1205 Seaway Dr. Customers on May 4, June 1, June 28, July 26 and Sept 21, 2011	4
46	Summary Chart of Dispensing Physician Assistants' Controlled Substances Prescriptions	2
47	Florida Department of Health Licensure Verification re: Physician Assistants Larry James, Michael Carpino, Peter Vo and Jeffrey Patane	4

VII. POSITION REGARDING HEARING SITUS

The Government requests to hold the hearing at the DEA Hearing Facility (DEAHF) located at 1550 Crystal Drive, Suite 901, Arlington, Virginia.

VIII. OTHER MATTERS

The Government reserves the opportunity to amend its instant pleading at a time and date specified by the presiding Administrative Law Judge. The Government requests the issuance of a protective order to prevent disclosure of the identities of Respondent's customers wherever such names and records are used in this proceeding.

The December 31, 2012 Orders for Prehearing Statements ordered the Government to present its position regarding the issue of consolidation and the possible *res judicata* effect of final factual and/or legal findings made by the Agency under Docket No. 13-1. The Government hereby incorporates by reference the separate filing on this issue regarding Docket Nos. 13-1, 13-9, 13-10, and 13-11.

IX. BEST ESTIMATE AS TO TIME REQUIRED TO PRESENT CASE

The Government anticipates requiring no more than three (3) days to present its case-in-chief, exclusive of cross-examination and rebuttal.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Michelle F. Gillice".

MICHELLE F. GILLICE

SCOTT LAWSON

Attorneys

Diversion & Regulatory Litigation

Office of Chief Counsel

Drug Enforcement Administration

8701 Morrisette Drive

Springfield, Virginia 22152

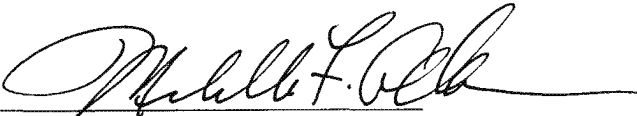
Dated: January 9, 2013

CERTIFICATE OF SERVICE

I hereby certify that on the date signed below, I caused the original and two copies of the foregoing **GOVERNMENT'S PREHEARING STATEMENT** to be hand delivered and faxed to the DEA Office of the Administrative Law Judges, and I caused a copy of the same to be sent, *via e-mail* and first class mail to counsel for Respondent at the following addresses:

Phil Perry
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Jan 9, 2013


Michelle F. Gillice
Diversion & Regulatory Litigation
Office of Chief Counsel
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, Virginia 22152

DEA REGISTRATION NUMBER BW6561270	THIS REGISTRATION EXPIRES 05-31-2013	FEE PAID \$551
SCHEDULES 2,2N,3 3N,4,5	BUSINESS ACTIVITY CHAIN PHARMACY	DATE ISSUED 05-12-2010
WALGREEN CO. DBA: WALGREENS # 04727 4950 S US HWY 1 FT PIERCE, FL 34952		

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
 UNITED STATES DEPARTMENT OF JUSTICE
 DRUG ENFORCEMENT ADMINISTRATION
 WASHINGTON, D.C. 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IS NOT VALID AFTER THE EXPIRATION DATE.

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Form DEA-223 (05/04)

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UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF

**WALGREEN, CO.
D/B/A WALGREENS #06997**

DOCKET NO. 13-11

**ADMINISTRATIVE LAW JUDGE
JOHN J. MULROONEY, II**

GOVERNMENT'S PREHEARING STATEMENT

Jonathan Novak
Scott Lawson
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Tel: 202.307.5434
Fax: 202.307.4946

Date: January 9, 2013

Pursuant to the December 31, 2012 Order for Prehearing Statements, the United States Department of Justice, Drug Enforcement Administration (“DEA” or “Government”), hereby submits its Prehearing Statement.

I. ISSUE

Whether DEA should revoke DEA Certificate of Registration BW8487438 issued to Walgreen Co. (“Respondent” or “Walgreens #06997”), pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f) and deny any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. § 823(f).

II. REQUESTED RELIEF

The Government requests revocation of Respondent’s DEA Certificate of Registration BW8487438.

III. PROPOSED STIPULATIONS OF FACT

1. Walgreens #06997 is registered with DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA Registration BW8487438 at 785 Lockwood Boulevard, Oviedo, Florida 32765.
2. DEA Registration Number BW8487438 expires by its terms on May 31, 2013.

IV. PROPOSED WITNESSES¹

1. Susan Langston
Diversion Program Manager
DEA Miami Field Division
2100 North Commerce Parkway
Weston, Florida 33326
2. Susan Slyker
Group Supervisor
DEA Orland District Office
300 International Parkway, Suite 424

¹ In addition to those witnesses noted in the Government’s Prehearing Statement, the Government reserves the right to call any witnesses noted on Respondent’s proposed witness list.

Heathrow, Florida 32746

3. Deborah George
Diversion Investigator
DEA Orland District Office
300 International Parkway, Suite 424
Heathrow, Florida 32746
4. Linda Stocum
Diversion Investigator
DEA Orland District Office
300 International Parkway, Suite 424
Heathrow, Florida 32746
5. Jeffrey Chudnow
Chief of Police
Oviedo Police Department
300 Alexandria Boulevard
Oviedo, Florida 32766
6. Mary E. Chmielewski, Ph.D.
Senior Personnel Psychologist
DEA Research & Analysis Group, Human Resources Division
600 Army Navy Drive
Arlington, Virginia 22202
7. Paul L. Doering, M.S.
Distinguished Service Professor of Pharmacy Practice, Emeritus
College of Pharmacy
University of Florida
101 South Newell Drive
HPNP Bldg 212
Room 3307
Gainesville, Florida 32611

V. SUMMARY OF TESTIMONY

1. Diversion Program Manager Susan Langston

DPM Langston will testify to her background, education and training as a DEA Diversion Investigator, Diversion Group Supervisor, and Diversion Program Manager. DPM Langston will testify about the problem of prescription painkiller diversion and abuse in Florida and the

proliferation of “pill mills” employing unscrupulous doctors who prescribe controlled substances outside the usual course of professional practice or for other than legitimate medical purposes. DPM Langston will testify that since at least 2009, the State of Florida has been epicenter of a notorious, well-documented epidemic of prescription drug abuse. The controlled substances most commonly associated with this epidemic are Schedule II pain relievers such as oxycodone; Schedule IV benzodiazepines, such as alprazolam; and Schedule IV muscle relaxers, such as carisoprodol.

DPM Langston will testify that in response the prescription pill epidemic, the Florida legislature passed a law in 2010 that restricted the ability of pain clinics to dispense controlled substances on site. DPM Langston will testify that once illicit prescriptions could not be filled at the pain clinic, pain clinic patients had to go to pharmacies to have their prescriptions filled. DPM Langston will testify that with the new law came a wave of new pharmacy applicants for DEA registrations.

DPM Langston will testify that upon receiving applications from retail pharmacy owners in South Florida, DEA regularly conducts pre-registration interviews to discuss pharmaceutical drug diversion. In June 2011, Walgreen Co. submitted an application for a new pharmacy DEA registration in Miami. In response to Walgreen’s new pharmacy application, DEA scheduled a meeting with Walgreens pharmacy representatives on August 19, 2011. DPM Langston will testify that in preparation for the meeting, DEA conducted a search of Walgreens Florida pharmacies oxycodone purchases through DEA’s Automation of Reports and Consolidated Orders System (ARCOS) which showed Walgreens #06997 significantly increased its oxycodone purchases between 2009 and 2011. DPM Langston will testify that such a dramatic increase in oxycodone purchases in such a short period of time is an indication to DEA

investigators that pharmaceutical diversion might be occurring and, coupled with the timing of the state law changes regarding pill mill dispensing, should have been an indication or “red flag” to Walgreens #06997 that it was likely dispensing oxycodone pursuant to illegitimate prescriptions.

DPM Langston will testify that at the August 19, 2011 meeting, DEA investigators met with Walgreens Co. officials to discuss Walgreens’ oxycodone sales in Florida and oxycodone diversion in Florida. Present on behalf of Walgreen Corporation were Dwayne Piñon (corporate in-house counsel), Ed Forbes (Market Loss Prevention Director), Wesley Rohn (Pharmacy District Supervisor), Joan Bustelo (Pharmacy District Supervisor), Anne-Marie Aldrick (Pharmacy District Supervisor), Cesar Cedeno (Pharmacy District Supervisor), Lakeisha Axem (Pharmacy Supervisor), Sandra Vazquesz (Pharmacy Supervisor), and Susan Thompson (Loss Prevention Manager).

DPM Langston will testify that at the August 19, 2011 meeting with Walgreens, she and Group Supervisor Gayle Lane discussed suspicious activity or “red flags” indicating that a controlled substance prescription may have come from a rogue pain management clinic, may not have been issued for a legitimate medical purpose, and/or may have been issued outside the usual course of professional practice. DPM Langston will testify that she and GS Lane identified suspicious activity or red flags related to customers indicating a risk of diversion. Such red flags included the following: people from out-of-state using questionable Florida Identification Cards, groups of patients with the same prescriptions for the more common drugs of abuse (typically oxycodone 30mg, oxycodone 15mg, Alprazolam 2mg and Soma, and one or two non-controlled prescriptions), groups of patients receiving the same prescriptions and same diagnosis, patients between 22 and 45 years old, patients traveling significant distances to the pharmacy and/or to

the pain management physician, and patients paying with cash. DPM Langston will testify that patients using with non-insurance discount cards to pay for controlled substance prescriptions is considered the equivalent of cash payments.

DPM Langston will testify that DEA also discussed physician red flags or suspicious conduct indicating the prescriptions were not issued for legitimate medical purposes or were issued outside the usual course of professional practice including: doctors writing prescriptions for the same common drugs of abuse, doctors using the same diagnosis for multiple prescriptions, and doctors whose specialties are unrelated to pain management (e.g., obstetrics, pediatrics, or ophthalmology) prescribing large quantities of Schedule II controlled substances. DPM Langston will testify that she and GS Lane informed Walgreens representatives of information compiled by ARCOS pertaining to Walgreens #06997 and other Walgreens pharmacies' purchases of oxycodone. DPM Langston will testify that Walgreens representatives were told that the average US pharmacy purchased 69, 500 dosage units of oxycodone in 2010, whereas the average Florida pharmacy purchased 134,000 dosage units of oxycodone in 2010. DPM Langston will testify that the summary chart entitled "2010 Top 100 Florida Walgreens Pharmacy Buyers of Oxycodone" was discussed at the meeting and provided to Walgreens official Dwayne Piñon. The ARCOS report will show that by then end of 2011, Walgreens #06997's oxycodone purchases increased to approximately 1,684,900 dosage units.

2. Group Supervisor Susan Slyker

DEA Diversion Group Supervisor ("GS") Slyker will testify about her training, background, and her experience as a Diversion Investigator and Group Supervisor. She will further testify substantially as follows:

In April 2012, as part of a larger investigation into the controlled substance dispensing practices of multiple pharmacies and other distributors of controlled substances owned by Walgreen Co., GS Slyker participated in the execution of an Administrative Inspection Warrant at Walgreens Store #06997 located at 785 Lockwood Boulevard, Oviedo, Florida 32765. During the execution of the warrant, GS Slyker conducted interviews with pharmacy staff and technicians, as well as supervised the collection of prescriptions for Schedule II controlled substances. During the execution of the warrant, DEA obtained hard copies of all Schedule II prescriptions on hand at the pharmacy. Subsequent to the execution of the warrant, DEA obtained electronic copies of Walgreens #06997 dispensing logs from Walgreens corporate headquarters.

During the course of the continuing investigation into the dispensing practices of Walgreens #06997, GS Slyker became aware of prescriptions that had been filled under DEA registrations belonging to Dr. Ronald Lynch (BL6686541) and Dr. Anthony Wicks (BW7987184). Both Lynch and Wicks were known to DEA due to other investigations. GS Slyker will testify that an examination of the dispensing logs for Walgreens #06997, provided to DEA by Walgreens, revealed two hundred sixty eight (268) prescriptions for controlled substances filled for Dr. Anthony Wicks under registration BW7987184 between December 2010 and July 2011. During this period of time, Dr. Wicks was registered at an address in Visalia, California, until his registration expired on May 31, 2011. Walgreens #06997 filled at least sixty four (64) prescriptions for Dr. Wicks subsequent to the expiration of his registration. Similarly, the dispensing log showed that on June 6, 2011, Walgreens 06997 dispensed 30 dosage units of vyvanse, a Schedule II controlled substance under the registration of Dr. Ronald Lynch. Dr. Lynch's DEA registration BL6686541 was revoked by the Administrator on January

20, 2011.

In the event of witness unavailability or unforeseen issues, GS Slyker may be called upon to testify to parts of the proposed testimony of Diversion Investigators Linda Stocum and Deborah George.

3. Diversion Investigator Deborah George

Diversion Investigator ("DI") George will testify to her background, education and training as a DEA Diversion Investigator. She will testify substantially as follows:

Subsequent to the execution of the Administrative Inspection Warrant at Walgreens #06997, DEA became aware of related investigations into criminal activity related to customers of Walgreens #06997. On April 18, 2012, DI George contacted the Oviedo Police Department to discuss any police investigations into activity at the pharmacy. On that date, DI George received, from the Oviedo Police Department, copies of multiple letters sent from the chief of police, Jeffrey Chudnow, to Walgreens #06997 informing the pharmacy that customers, to whom they had dispensed controlled substances, were arrested and charged criminally with illegal distribution of the very controlled substances dispensed by Walgreens #06997. Additionally, DI George obtained copies of the same letters, as sent from Chief Chudnow to the Chairman and to the CEO of Walgreens, informing Walgreens corporate headquarters of the arrests taking place at Walgreens #06997.

Upon receiving and examining the letters, DI George then compared the names of the arrestees identified in the Chudnow letters to the dispensing logs for Walgreens #06997 in order to corroborate the information provided in the letters. DI George was able to corroborate that the arrestees were in fact supplied with controlled substances from Walgreens #06997. These

customers of Walgreens #06997 included: Sean Reynolds, arrested November 11, 2010 for illegal distribution of Xanax; Frederick J. Goepel, arrested January 12, 2011 for illegal distribution of oxycodone; Clinton Brekke, arrested January 20, 2011 for possession with intent to sell oxycodone; Valerie Brekke, involved in the arrest of Clinton Brekke for possession with intent to sell oxycodone; Matthew S. Miller and Timothy Kemp Dawson, arrested January 21, 2011 for illegal distribution of oxycodone; Brian Lee Kemm, arrested on January 26, 2011 for illegal distribution of oxycodone; and, Staci Lynn Starling and Anna Marie Girst, involved in the arrest of Kemm as the customers purchasing illegal controlled substances.

DI George also found that despite the content of the letters from Chief Chudnow, Walgreens #06997 filled controlled substance prescriptions for some of the arrested customers subsequent to these arrests and notifications to Walgreens #06997. Clinton Brekke was arrested on January 20, 2011 and Chief Chudnow notified Walgreens in a letter dated January 21, 2011. Subsequently, Walgreens #06997 filled prescriptions for Mr. Brekke on March 13, April 7 and April 11, 2011. In the same letter regarding the arrest of Clinton Brekke, Valerie Brekke was identified as involved in the oxycodone-related arrest. Nonetheless, Walgreens #06997 filled prescriptions for Valerie Brekke for oxycodone on March 16 and April 25, 2011. In Chief Chudnow's January 27, 2011 letter, Staci Lynn Starling was noticed as a party purchasing oxycodone from Brian Lee Klemm. Nonetheless, Walgreen's #06997 dispensed alprazolam, hydromorphone and oxycodone to Ms. Starling on February 15, March 14 and April 13, 2011.

In the event of witness unavailability or unforeseen issues, DI George may be called upon to testify to parts of the proposed testimony of Diversion Investigator Linda Stocum and GS Slyker.

4. Diversion Investigator Linda Stocum

Diversion Investigator (“DI”) Stocum will testify to her background, education and training as a Diversion Investigator with the Drug Enforcement Administration. She will further testify as follows:

As part of the existing investigation into several Walgreens pharmacies in Florida and the Walgreens Distribution Center in Jupiter, Florida, DEA obtained hard copies of prescriptions filled at those pharmacies between January 2010 and April 2012. DEA also obtained controlled substances dispensing logs from the pharmacies. Based on a review of the documents obtained from the Administrative Inspection Warrants as well as the continuing DEA investigation into Walgreens, DEA requested copies of all controlled substance prescriptions filled by the Walgreens Mail Order facility out of Orlando, Florida. DEA obtained copies of all prescriptions filled by the facility between January 1, 2010 and April 2012.

After a review of the Mail Order prescriptions and a comparison to ARCOS information on controlled substance purchases made under the Mail Order DEA registration, DEA contacted the facility to inquire about large discrepancies between controlled substances ordered and prescriptions filled. At this time, Walgreens informed DEA that in addition to operating a mail order facility, Walgreens also runs their central pharmacy operations (“Central Fill”) out of the same Orlando facility. DI Stocum will explain how the Central Fill facility operates: namely, that a Walgreens pharmacy will send certain prescriptions to the facility to be filled, and the facility will then send the filled prescription back to the pharmacy for dispensing to the ultimate customer.

DI Stocum and DI Deborah George conducted an on-site visit to the Central Fill facility on June 19 and June 21, 2012. DI Stocum will testify about the site visit and what she learned

about the facility and operations at that time. She will testify that the Walgreens Central Fill staff provided verbal explanations of the operations conducted at the facility, but were unable to provide DEA with documentation regarding filled prescriptions.

Subsequent to the on-site visit to Central Fill, DEA obtained the dispensing logs for Central Fill from Walgreens. DI Stocum compared the information in the Central Fill dispensing log to the prescriptions obtained from Walgreens #06997 during the execution of the April 2012 Administrative Inspection Warrant. DI Stocum found that the prescriptions sent from Walgreens #06997 to Central Fill lacked notation stating that the prescription was sent to Central Fill, as required under 21 C.F.R. § 1306.27(a)(1).

On October 25, 2012, DI Stocum visited Walgreens #06997 to review the pharmacy's prescription records pertaining to prescriptions reported as filled by Central Fill. DI Stocum will testify that she presented a Notice of Inspection to Pharmacy Manager Dan Heinis, and that Heinis assisted DEA in its inspection. DI Stocum requested to see prescriptions that she knew to have been filled by Central Fill based on the Central Fill dispensing log, and she testified about these prescriptions. Heinis assisted DI Stocum by providing the prescriptions. None of the prescriptions were marked as having been filled by Central Fill. Heinis stated that he could not identify which prescriptions were filled by Central Fill and which were filled by Walgreens #06997. Heinis discussed with DEA how and why a prescription might be filled by Central Fill instead of Walgreens #06997. Heinis also noted that when a prescription was filled by Central Fill but was not picked up by the ultimate customer, the controlled substance is automatically added to the retail store's inventory.

DI Stocum will testify about the practical effect of this aspect of Walgreens' practice; namely the complications created in attempting to perform an audit or otherwise capture the full

picture of tracking controlled substance distributions and dispensing.

In the event of witness unavailability or unforeseen issues, DI Stocum may be called upon to testify to parts of the proposed testimony of Diversion Investigator George and GS Slyker.

5. Oviedo Police Department Chief of Police Jeffrey Chudnow

Chief Chudnow will testify about his background, training and experience as a police officer and as the Chief of Police for Oviedo, Florida. Chief Chudnow will testify about the effects that the diversion of controlled substances has had on the city of Oviedo, as evidenced by increases in, among other things, crime rates and overdoses. Chief Chudnow will testify about his department's knowledge of Walgreens #06997, as well as another Walgreens store within the city limits, as centers for illicit controlled substance sales and use.

The Oviedo Police Department (OPD) made numerous arrests for illegal distribution of controlled substances in 2010 and 2011 related to controlled substances dispensed at the two Walgreens pharmacies, Walgreens #06997 and Walgreens #04251, with many of the illicit transactions preceding these arrests occurring in the parking lots of the stores. Chief Chudnow will testify that it was his practice following one of these arrests to send a letter to the pharmacy which dispensed the controlled substance being diverted, notifying them of the details and asking for the pharmacy's assistance in preventing future diversion. Chief Chudnow sent dozens of these letters, at least five of which will be offered into evidence, because Walgreens #06997 continued to dispense to some of these individuals even after being notified of their arrest.

On February 10, 2011, Chief Chudnow met with Ed Lanzetti, Walgreens Market Loss Prevention Director, and another Walgreens official. At the meeting, Chief Chudnow presented Mr. Lanzetti with numerous statistics and facts regarding controlled substance arrests related to

Walgreens' two Oveido pharmacies. These statistics included numbers and types of drug-related arrests, types of controlled substances seized per arrest, and statistics showing the names of doctors whose prescriptions were related to diversion arrests. Despite being given this information, Walgreens #06997 continued to fill prescriptions for these associated doctors subsequent to the February meeting with Chief Chudnow.

On March 15, 2011, Chief Chudnow sent letters to Alan G. McNally, Chairman of Walgreens Corporation and to Gregory D. Wasson, President and CEO of Walgreens Corporation, informing them about the numerous controlled substance arrests taking place at the Oveido Walgreens pharmacies and the effects on the community of Oveido, and asking for their assistance in stopping these problems. Chief Chudnow never received any response to his request for assistance from anyone at Walgreens.

6. Mary E. Chmielewski, Ph.D.

Mary E. Chmielewski, Ph.D., is a Senior Personnel Psychologist who works in the Research & Analysis Group of DEA's Human Resources Division. Dr. Chmielewski will be offered by the Government as an expert in statistical analysis related to the purchase of controlled substances by a registered pharmacy. In the course of her official duties, Dr. Chmielewski frequently performs statistical analysis and interpretation. Dr. Chmielewski has performed a statistical analysis of the ARCOS data related to the oxycodone purchased by Walgreens #06997 from January 2006 through December 2011. Dr. Chmielewski will testify that the volume increase of oxycodone purchases observed over this period of time was statistically significant.

7. Professor Paul Doering

Professor Doering will testify regarding his education, background, training, and experience as a pharmacist. Prof. Doering will testify that he (1) is a registered pharmacist in the states of Florida and North Carolina, (2) is certified as a Consultant Pharmacist in Florida, (3) previously practiced in the community pharmacy setting (4) has been a professor at the University of Florida's School of Pharmacy for the past 35 years, (5) currently serves at the University of Florida's College of Pharmacy as Distinguished Service Professor of Pharmacy Practice, Emeritus, and (6) for 28 years was either Director or Co-Director of the University of Florida's Drug Information and Pharmacy Resource Center, a telephone access service through which health professionals can get obtain information about drugs or drug therapy. Prof. Doering will further testify about his experiences serving as an expert consultant and witness in a number of criminal, civil, and administrative proceedings. Prof. Doering will provide expert witness testimony as detailed below.

Prof. Doering will testify about the education and training pharmacists receive in pharmacy school, including learning the fundamentals of both state and federal pharmacy law as it relates to the filling and dispensing of prescription drugs in general, and controlled substances in particular. He will further testify about training pharmacists receive in the application of those laws to real life situations. He also will discuss the coverage of these topics in Florida's pharmacist licensing exam.

Prof. Doering will testify about the epidemic of prescription drug diversion and abuse in the state of Florida. He will discuss the in 2011 State of Emergency declared by the Florida Surgeon General which was issued in effort to prevent the many drug overdose deaths from

controlled substances. The controlled substances commonly associated with this epidemic are Schedule II pain relievers such as oxycodone; Schedule IV benzodiazepines, such as alprazolam; and Schedule IV muscle relaxers, such as carisoprodol. Prof. Doering will testify about the overdose deaths due to oxycodone and benzodiazepines identified by the 2011 Florida Medical Examiners Report. He will testify that pharmacists are in a key position to reverse this trend of this epidemic.

Prof. Doering will further testify about the pharmacist's role in the distribution of prescription drugs that are controlled substances. He will testify about the dangerous propensities of certain controlled substances, in particular opiates and opioids such as oxycodone and benzodiazepines such as diazepam (Valium) and alprazolam (Xanax). Prof. Doering will testify that when controlled release opiate products are prescribed correctly, patients should not need to be on concurrent around the clock opiates for break through pain.

Prof. Doering will discuss the responsibilities of pharmacists in filling controlled substances prescriptions. Prof. Doering will testify about the review and analysis pharmacists should undertake before certifying any such prescription for release to the patient, including checking the licensing status of prescribers and evaluating whether the prescription presented to them is for a legitimate medical purpose and issued by a properly registered practitioner in the usual course of professional practice.

Prof. Doering will testify about the "red flags" used by pharmacists as indicators of diversion and abuse. Because of the enormous abuse and diversion associated with oxycodone, the mere fact that an oxycodone prescription is being presented should put the pharmacist on full-alert to ensure that the prescription is valid. Oxycodone prescribed in combination with alprazolam and/or with carisoprodol, a popular "cocktail" combination in illicit use, should raise

even more scrutiny with a pharmacist.

He will discuss certain patterns or circumstances that are consistent with drug diversion schemes that, in his opinion, a diligent pharmacist can observe, as well as the techniques that help the pharmacist detect drug diversion. Examples of such patterns or circumstances include, but are not limited to, patients who pay with cash, patients who are prescribed large quantities of controlled substances, patients who share the same address, patients who are prescribed the same numbers and types or combinations of drugs, and patients who live a distance from the prescribing practitioner and/or pharmacy, including out-of-state patients and/or practitioners. His testimony also will cover the criteria appearing in the 2010 Edition of the Drug Enforcement Administration's Pharmacist's Manual, which provided guidance to pharmacists of indicators that a prescription was not issued for a legitimate medical purpose. Prof. Doering will testify that when taken together these "red flags" create enough suspicion that the reasonable and prudent pharmacist would refuse to fill the prescriptions.

Additionally, Prof. Doering will testify about the information he was provided by the DEA to review and analyze concerning Walgreens #06997. This information included, but is not limited to: Walgreens #06997's dispensing log, copies of prescriptions and prescription labels for Schedule II controlled substances dispensed by Walgreens #06997, and copies of the letters sent by Chief Jeffrey Chudnow of the Oviedo Police Department to Walgreens #06997.

Prof. Doering will testify that based on his education, training, and experience as a pharmacist, his review and analysis of the DEA information he received shows that Walgreens #06997's pharmacists ignored "red flags" of drug diversion or abuse and filled prescriptions that were issued outside the usual course of medical practice. He will testify that some, but not all red flags can be resolved by a pharmacist. In those instances, when red flags are unresolvable, a

reasonable pharmacist exercising due care would refuse to fill the prescription.

Prof. Doering will discuss his analysis of Walgreens #06997's controlled substance dispensing between January 1, 2010 and April 4, 2012. He will testify that while the number of dosage units ordered by a pharmacy does not confirm illegal activity, the larger the number of dosage units ordered and dispensed, the more suspicion is aroused. He will testify that the sheer number of controlled substance prescriptions filled per day can be an indicator that something might be awry. Prof. Doering will discuss the increase in Walgreens #06997's average daily dispensing of controlled substances. Prof. Doering will testify that a pharmacy such as Walgreens #06997 would have expected its customer base to reach a plateau. Any drastic change in volume should cause a pharmacy to step back and figure out why. Professor Doering will testify that the rise in oxycodone dispensing by Walgreens #06997 in 2010-2011, coincides with the change in Florida law, which restricted controlled substance dispensing by practitioners.

Professor Doering will testify about various other categories of red flags that appear in the dispensing logs, including customers arriving on the same day, living at the same address, and presenting prescriptions from the same doctor; customers traveling from distances over 50 miles away to have their prescriptions filled; customers prescribed a cocktail of highly abused controlled substances; and large numbers of customers presenting prescriptions from the same doctors, who primarily or exclusively prescribe highly abused controlled substances.

VI. PROPOSED DOCUMENTS

1. DEA Certificate of Registration BW8487438 (1 page)
2. Chart entitled "2010 Top 100 Florida Walgreens Pharmacy Buyers of Oxycodone" (1 page)

3. Administrative Inspection Warrant (14 pages)
4. Certification of Registration History for DEA Certificate of Registration BW7987184 (2 pages)
5. Certification of Registration History for DEA Certificate of Registration BL6686541 (2 pages)
6. Dispensing Log for Walgreens #06997 (944 pages)
7. Excerpts of Dispensing Log: Wicks (8 pages)
8. Excerpts of Dispensing Log: Cocktail (20 pages)
9. Excerpts of Dispensing Log: Distances Traveled (12 pages)
10. Excerpts of Dispensing Log: Customers Coming From the Same Address (10 pages)
11. Copies of prescriptions sent from Walgreens #06997 to the Walgreens Central Fill facility
12. Letters from Oviedo Police Department to Walgreens (9 pages)
13. Chudnow Desktop Notes (2 pages)
14. Brekke Letters, Dispensing Logs and Prescriptions (30 pages)
15. Starling Letters, Dispensing Logs and Prescriptions (17 pages)
16. Oviedo Police Department Surveillance Statistics (2 pages)
17. Oviedo Police Department Arrest Statistics (1 page)
18. Curriculum Vitae of Mary E. Chmielewski, Ph.D. (5 pages)
19. Comparison of Total Dosages of Oxycodone by Year: Walgreens #06997 (2 pages)
20. Curriculum Vitae of Professor Paul Doering (31 pages)

VII. OTHER MATTERS

The Government reserves the opportunity to amend its instant pleading at a time and date specified by the presiding Administrative Law Judge. The Government requests the issuance of

a protective order to prevent disclosure of the identities of Walgreens #06997's customers wherever such names and records are used in this proceeding.

The December 31, 2012 Orders for Prehearing Statements ordered the Government to present its position regarding the issue of consolidation and the possible *res judicata* effect of final factual and/or legal findings made by the Agency under Docket No. 13-1. The Government hereby incorporates by reference the separate filing on this issue regarding Docket Nos. 13-1, 139, 13-10, and 13-11.


VIII. POSITION REGARDING HEARING SITUS

At this time, the Government does not request a change of location for the hearing.

IX. BEST ESTIMATE AS TO TIME REQUIRED TO PRESENT CASE

The Government anticipates requiring no more than two (2) days to present its case-in-chief, exclusive of cross-examination and rebuttal.

Respectfully submitted,



JONATHAN P. NOVAK
Attorney
Diversion & Regulatory Litigation
Office of Chief Counsel

Date: January 9, 2013

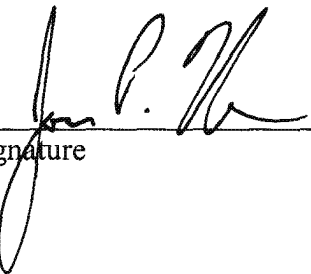
CERTIFICATE OF SERVICE

I hereby certify that on the date signed below, I caused the original and two copies of the foregoing **GOVERNMENT'S PREHEARING STATEMENT**, to be hand delivered and faxed to the DEA Office of the Administrative Law Judges, and I caused a copy of the same to be sent, *via e-mail* to counsel for Respondent at the following addresses:

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Miami, Florida 33131
Fax: 305-377-3001
Email: DWeinstein@cspalaw.com

8/9/13
Date


Signature

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BW8487438	05-31-2013	\$551

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3 3N,4,5	CHAIN PHARMACY	05-12-2010

WALGREEN CO.
DBA: WALGREENS # 06997
785 LOCKWOOD BLVD
OVIDO, FL 32765

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C. 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (05/04)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BW8487438	05-31-2013	\$551

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3 3N,4,5	CHAIN PHARMACY	05-12-2010

WALGREEN CO.
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